IBD-live: Teenagers at the wheel.

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Use of IBD-live for 1 year: 1. Reduces the relapse rate from 40% to 25%; 2. Increases quality of life (assessed with the IMPACT-III questionnaire).

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29580

Bron
Nationaal Trial Register

Aandoening

inflammatory bowel disease; relapse; Crohn’s disease; ulcerative colitis; eHealth; telemedicine; children; calprotectin; home monitoring

Ondersteuning

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Overige ondersteuning: (1) ZonMw (the Netherlands Organisation for Health Research and Development)
(2) Innovatiefonds Zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is relapse rate per group. Relapse is defined as moderate-severe disease activity in combination with fCal >250 ug/g, necessitating induction therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and Aims:

Conventional follow-up of teenagers with inflammatory bowel diseases [IBD] is done during scheduled outpatient visits regardless of how well the patient feels. We designed a telemonitoring strategy for early recognition of flares and compared its efficacy with conventional follow-up.

Methods:

We used a multicentre randomized trial in patients aged 10–19 years with IBD in clinical remission at baseline. Participants assigned to telemonitoring received automated alerts to complete a symptom score and send a stool sample for measurement of calprotectin. This resulted in an individual prediction for flare with associated treatment advice and test interval. In conventional follow-up the health check interval was left to the physician’s discretion. The primary endpoint was cumulative incidence of disease flares. Secondary endpoints were percentage of participants with a positive change in quality-of-life and cost-effectiveness of the intervention.

Results:

We included 170 participants [84 telemonitoring; 86 conventional follow-up]. At 52 weeks the mean number of face-to-face visits was significantly lower in the telemonitoring group compared to conventional follow-up [3.6 vs 4.3, $p < 0.001$]. The incidence of flares [33 vs 34%, $p = 0.93$] and the proportion of participants reporting positive change in quality-of-life [54 vs 44%, $p = 0.27$] were similar. Mean annual cost-saving was €89 and increased to €360 in those compliant to the protocol.

Conclusions:

Telemonitoring is as safe as conventional follow-up, and reduces outpatient visits and societal costs. The positive impact on quality-of-life was similar in the two groups. This strategy is attractive for teenagers and families, and health professionals may be interested in using it to keep teenagers who are well out of hospital and ease pressure on overstretched outpatient services.

Doel van het onderzoek

Use of IBD-live for 1 year:

1. Reduces the relapse rate from 40% to 25%;

2. Increases quality of life (assessed with the IMPACT-III questionnaire).

Onderzoeksopzet

Primary outcome at 12 months.

Onderzoeksproduct en/of interventie

Intervention:

Teenagers assigned to IBD-live will use the flarometer -an automatic cumulation of disease activity and fecal calprotectin (fCal)- to estimate probability of relapse. In case of high risk treatment is intensified in accordance with national guidelines; low risk means that maintenance therapy is unchanged; and intermediate risk requires optimisation of drug adherence.

Control:

Usual care consists of fixed, 3-monthly contacts with the IBD-team and includes a physicians' rating of disease activity and blood sampling.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible patients are those: Aged 10 to 19 years, with quiescent IBD for more than 3 months before study enrolment, with IBD diagnosed (according to the Porto criteria) more than 6 months before enrolment, who have access to internet and weighing scale, with knowledge of the Dutch language, and with an adult caregiver who is willing to actively support participation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Potential participants will be excluded from the study if any of the following conditions occur:

1. Maintenance treatment with infliximab or adalimumab (for unavoidable frequent contact with health providers);

2. Presence of ileostomy or ileoanal pouch (as fCal cut-off is not validated for small bowel feces);

3. Presence of active perianal Crohn’s disease;

4. Any comorbidity at the time of enrolment that requires hospitalization or frequent blood sampling.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	180
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3601
NTR-old	NTR3759
Ander register	Innovatiefonds / ZonMw / Fonds NutsOhra : 2509 / 80-83700-98-131006 / 1301-002;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
https://doi.org/10.1186/s13063-015-0787-x
https://doi.org/10.1093/ecco-jcc/jjx169